

Application No. 10/595,544
Amendment Dated 6/26/2009
Reply to Office Action of 03/10/2009

REMARKS/ARGUMENTS

By this Amendment, claims 1-9, and 14-15 are canceled, claims 10, 13, and 17-18 are amended. Claims 10-13, and 16-18 are pending.

Citations to the Specification are directed to U.S. Patent Application No. 2008/0281093 (Parthasaradhi Reddy et al.).

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 10-13, and 16-18 are pending. Applicant hereby affirms the provisional election with traverse of Group II, claims 10-13 and 16-18, which was originally made by telephone to Examiner Berch on October 23, 2008. The Examiner sets forth that the special technical feature of Group I is the silylation process; that the special technical feature of Group II is the acylation of an amine. The Examiner further sets forth that Group II in fact has a de-silylation process, and that each process can be performed without the other. The Examiner argues that the only commonality is the compound of Formula II, which is not unobvious over the prior art, and that burden is seen by the separate classification. Group I is classified in 556/418. Group II is classified in 540/215.

The traversal is on the grounds that in the instant case, the special technical feature which links the claimed inventions are the novel processes wherein the claimed methods are not found in the prior art. Since the inventions are linked by this special technical feature they are a single inventive concept. In addition, this special technical feature defines an advance over the prior art because the claimed methods are not taught in the prior art. In addition, there would not be a serious burden on the Examiner to search all the claims. Since the special technical feature which links the inventions is a contribution over the prior art, the claims have unity of invention under PCT Rule 13.1, and thus the requirement for restriction should be withdrawn. Reconsideration of the restriction requirement is respectfully requested.

Applicant reserves the right under 35 USC § 121 to file divisional applications for the nonelected claims.

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Rejection Under 35 USC § 112 second paragraph

Claims 13 and 17-18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner sets forth that claims 13 and 17-18 are not written right, allegedly because a hydrate is a solvate, and the hydrate which is precipitated is not a "de-solvated" product. The Examiner suggests the limitation "filtering the cefprozil hydrate". Without acquiescing to the propriety of the Examiner's rejections, the claims have been amended herein solely in an effort to expedite prosecution.

Claims 10-13, 16-18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ. 81, 94 (CAFC 1986) it was stated:

".. if the claims read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." (citing Shatterproof Glass Corp. v. Libbey Owens Ford. Co. 225 USPQ 634, 641 (CAFC 1985)).

Thus, whether a claim is in compliance with the second paragraph of § 112 requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.

In the present situation, The Examiner sets forth that it is unclear what the chiral status of the carbon attached to the alpha-amino group is. The reagent II and the intermediate VII both show no chiral indication, meaning that this is a racemic mixture. Thwe Examiner admits that the final product of Formula I has a chiral indicator in the structural formula (the dashed line to the amino), but not in the canonical name given for that structure, which immediately precedes it. However, there is in parenthesis the name "cefprozil", and that drug is chiral at that position.

However, the Specification discloses a process of preparing cefprozil, and that the use of the silyl protected compound of formula II in the preparation of cefprozil is practically advantageous (see ¶[0011]). In addition, the structure of Formula I is clear from the claim.

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Accordingly, one skilled in the art would understand what is claimed when the claim is read in light of the specification.

Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 USC § 112 first paragraph

Claims 10-13, 16-18 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejection is respectfully traversed.

The Examiner sets forth that the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner argues that as written, the claims appear to use a racemic reagent to obtain a chiral product, but with no resolution step provided. The Examiner alleges that this is not enabled.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224 (CCPA 1971).

However, here, the claims are enabled because there is not any reason to doubt the objective truth of the statements contained in the Specification for enabling support. The Specification discloses the manner and process for making and using the claimed invention, including working examples which show the efficacy of the claimed invention. For example, the Specification discloses a process of preparing cefprozil (see ¶[0011]):

Use of silylated mixed anhydride of formula II in the preparation of cefprozil and pharmaceutically acceptable salts thereof is also novel and provides another aspect of the present invention. Cefprozil and pharmaceutically acceptable salts also include their hydrates or solvates.

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Additionally, the Specification discloses (see ¶[0011]):

The use of the silyl protected compound of formula II avoids the self-acylation and so, strict control of quantity of silyl protected intermediate is not required and controlled addition of the reactant is not required; and so, the use of the silyl protected compound of formula II in the preparation of cefprozil is practically advantageous.

Thus the Specification provides guidance to one of skill in the art to practice the claimed method of preparing cefprozil. Given the teachings of the Specification, the quantity of experimentation required is not excessive in view of the subject matter of the claims. The Specification sets forth several methods for producing cefprozil. Working Examples are provided, as well as detailed information as to the methods. This information can be used by one of ordinary skill in the art to practice the claimed process, without undue experimentation.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

* * *

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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